

**REMARKS/ARGUMENTS**

**Remarks**

The Examiner's communication of October 4, 2004, together with the references cited therein, has been given careful consideration. After such consideration, and in an earnest effort to place this application in condition for allowance, Applicant has by the foregoing amendments, amended Claim 1 and its dependent Claims 2 through 8 to more clearly define patentable invention over the references of record. Applicant also hereby submits the attached Terminal Disclaimer in response to the double patenting rejection of this application over the claims of commonly assigned U.S. Patent No. 6,692,510. With these amendments, and with the submission of the Terminal Disclaimer, it is believed that all of the claims in this application, to wit, Claims 1 through 9 clearly define patentable invention over the cited references.

**The Invention**

The present invention is directed toward an aneurysm embolization device and deployment system for use in occluding the flow of blood within a vessel, and more particularly within an aneurysm, of the human body. The deployment system includes a catheter having a small diameter lumen extending therethrough and being formed of a material which is sufficiently flexible to pass through the vessels of the body. The embolization device includes a headpiece and a central connecting member which takes the form of a flexible fiber which is connected to the distal end of the headpiece. At least one spherical member, and preferably a plurality of spherical members, which take the form of small diameter balls, are carried by the flexible fiber. The proximal section of the headpiece is disposed within the distal section of the deployment catheter so that when fluid pressure is applied to the lumen of the catheter the catheter releases the headpiece at the preselected position within the vessel. It is important to appreciate that the present invention serves to embolize, or fill an aneurysm which exists in the

Serial No. 10/729,523

wall of a vessel and in which the multiple spherical members which are carried by a very flexible fiber serve to pack into the aneurysm and prevent, or reduce, the flow of blood through the aneurysm to thereby cause less pressure to be applied within the interior of the aneurysm. Ultimately, the aneurysm should reduce in size and should therefore be less apt to rupture.

#### The Cited References

The cited U.S. Patent No. 5,980,548 to Evans, et al., is directed toward a system for revascularization of the human heart. More particularly, this reference teaches the use of various shaped "inserts" which are inserted into the wall of the myocardium in order to initiate the growth of new vessels within the wall of the heart. As illustrated in Figures 9A through 9S, it is possible to use one of many different shapes or configurations of inserts to cause this revascularization process to be initiated. There is no suggestion in this reference of providing a device which would embolize an aneurysm which exists in the wall of a vessel, and in fact the "inserts" are actually inserted into an area of the myocardium wall which is completely filled with tissue prior to the insertion of the insert. Still further, there is no suggestion in this reference of applying a fluid pressure to a deployment catheter in order to drive the inserts into the myocardium. It is doubtful that it would even be possible to create enough pressure within a catheter to drive these inserts into tissue of the myocardium. Certainly, it would not be obvious.

The cited U.S. Patent No. 6,299,619 to Greene, et al., discloses a plurality of cylindrically shaped embolizing elements disposed at spaced intervals along a filament. The embolizing device may then be placed within a catheter and is then pushed through the catheter until the device is pushed out of the distal end of the catheter and into the aneurysm. The embolizing device including the cylindrically shaped embolizing elements then serve to partially fill the aneurysm in order to reduce blood flow through the aneurysm. There is no suggestion in

Serial No. 10/729,523

this reference of an embolization device which includes a plurality of small diameter spherical balls placed along a flexible fiber, nor is there any suggestion in this reference of a deployment system which utilizes a fluid pressure to cause the deployment catheter to release the embolization device at a preselected position.

The cited U.S. Patent No. 3,095,877 to Rowan, et al., discloses the concept of packing a deep wound with a plurality of absorbent balls secured to a thread in order to prevent heavy bleeding, or serious hemorrhage of the wound. This patent does not appear to be particularly pertinent to the field of embolization devices for aneurysms.

Similarly, the cited U.S. Patent No. 5,833,642 to McCabe, et al., discloses a device for absorbing wound exudates which is comprised of a series of interconnected square or rectangular perforated bags made of a substance having a maximum thickness of one millimeter. This device for absorbing fluid from wounds would not appear to be particularly relevant to the subject invention.

#### The Rejection

The Examiner has rejected Claims 1 through 9 under the “judicially created doctrine of obviousness-type double patenting as being unpatentable over . . . U.S. Patent No. 6,692,510.” Applicant has submitted the attached Terminal Disclaimer terminally disclaiming that portion of the patent which would issue from the subject patent application which extends beyond the expiration of the commonly assigned U.S. Patent No. 6,692,510. It is believed that with the submission of this Terminal Disclaimer, this rejection has been overcome by Applicant.

The Examiner has rejected Claims 1, 2, 5, 7 and 8 under “35 U.S.C. 102(b) as being anticipated by Evans, et al.” The Examiner has indicated that “The patent to Evans et al discloses a device capable of occluding blood flow. . .” Actually, the “inserts” disclosed by the

Evans reference do not serve the purpose of occluding blood flow, but in fact are inserted into solid tissue in the wall of the myocardium in order to initiate the growth of blood vessels.

Contrary to the embolization device of the present invention, the “inserts” of Evans are pressed into a region which is entirely filled with tissue in order to recanalize the tissue by causing vessels to grow through the tissue.

The subject invention is directed toward an embolization device and method of use for partially filling an aneurysm which may exists in the wall of a vessel, which aneurysm is somewhat “balloon shaped” and is generally hollow except for the flow of blood through the aneurysm. By placing an embolic device, such as that disclosed and claimed in the present invention, into an aneurysm the device tends to reduce the blood flow through the aneurysm and permit tissue to ingrow around the embolic device in order to ultimately fill, or partially fill, the hollow aneurysm. While it is true that one of the many devices such as that shown in Figure 9F of the Evans reference appears to show cylindrical balls placed along a cable for providing recanalization of the heart wall, this device fails to disclose or suggest the claimed invention. For example, there is no disclosure in this reference of an embolization device, there is no disclosure of a deployment catheter for placing an embolization device within an aneurysm in which a fluid pressure is applied to the lumen of the catheter in order to release the embolization device. Also, the catheter disclosed in the Evans, et al. reference would appear to be a rather stiff and rigid device as opposed to a deployment catheter formed of a material which is sufficiently flexible to pass through the vessels of the body. This reference which discloses a medical device used for a vastly different purpose, does not teach a structure of the type as positively claimed in the subject application.

Claims 1 through 9 have been rejected “under 35 U.S.C. 103(a) as being unpatentable over Greene et al. . . in view of Evans et al. . . Rowan et al. . . and McCabe et al.” It appears that the Examiner has taken a group of four references, of which only one relates to the subject matter of the present patent application, and has combined these references in an attempt to reconstruct Applicant’s invention. Of these four references, Greene, et al. is the only one that remotely relates to an embolization device and deployment system for the embolization device. As discussed, the Evans reference relates to “inserts” to be placed in the wall of the myocardium; the Rowan, et al. reference relates to a surgical packing device for large wounds; and, the McCabe, et al. reference relates to a device for absorbing wound exudates. These later references would not appear to be particularly relevant to the subject invention.

Of these four references, the patent to Greene, et al. discloses an embolization device which includes a series of highly expansible cylindrical embolization elements placed on a filament. This device presumably would provide embolization of an aneurysm, however, the structure of the device is quite different from that disclosed in the present application and there is no suggestion in this reference of a deployment system as is disclosed and claimed in the present application. For example, there is no suggestion in this reference of an embolic device having a headpiece and a flexible fiber which carries a plurality of small cylindrical balls for purposes of embolization. Similarly, there is no suggestion in this reference of a deployment catheter in which a fluid pressure is applied to the lumen of the catheter in order to release the embolization device at a preselected position. These features are positively recited in Claim 1 and its dependent Claims 2 through 8 and are neither disclosed nor suggested by this reference or any of the other cited references.

Serial No. 10/729,523

With respect to Claim 9, again, the cited references do not disclose nor teach the method of providing an aneurysm embolization device including a headpiece coupled to the distal end of a deployment catheter in which the embolization device includes a central connecting member which takes the form of a flexible fiber and is attached to the headpiece and also includes one or more spherical members, or balls, which are carried by the fiber and subsequently introducing the deployment catheter into a vessel and releasing the aneurysm embolization device at a preselected cite. These method steps are neither disclosed nor suggested by the cited references.

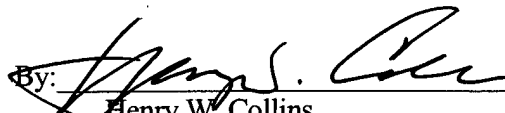
Accordingly, the present application discloses an aneurysm embolization device and deployment system which is quite different from that disclosed in the cited references. The claims in this application positively recite a structure which is not present in these references.

Accordingly, it is submitted that none of the cited references taken separately, or in any combination, thereof suggest the concept of the present invention.

In view of the foregoing remarks, Applicant respectfully submits that Claims 1 through 9 clearly define patentable invention over the teachings of Evans, et al., Greene, et al., Rowland and McCabe, et al.

It is respectfully submitted that this application is now in condition for allowance and notification of such action is respectfully solicited.

Respectfully submitted,

By:   
Henry W. Collins  
Reg. No. 25,039

Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933-7003  
(786) 313-2707  
Dated: March 30, 2005